DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2014

Teleflex Medical Incorporated
c/o Mr. Jim Cochie
Sr. Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, NC 27709

Re: K141214
Trade/Device Name: Hudson RCI® AquaPak® Prefilled Nebulizers
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer (Direct Patient Interface)
Regulatory Class: Class II
Product Code: CAF
Dated: November 14, 2014
Received: November 20, 2014

Dear Mr. Cochie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141214

Device Name

Hudson RCI® AquaPak® Prefilled Nebulizer

Indications for Use *(Describe)*

Hudson RCI® AquaPak® Prefilled Nebulizer adds sterile water or saline solution in aerosol form to a patient's breathing gases. It may be used with pediatric (ages 2 years and above) and adult patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 29 – 510(k) Summary - Updated

510(k) SUMMARY

Hudson RCI® AquaPak® Prefilled Nebulizers

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-8083
Fax: 919-433-4996

B. Contact Person

James Cochie
Sr. Regulatory Affairs Specialist

C. Date Prepared

August 26, 2014

D. Device Name

Trade Name: Hudson RCI® AquaPak® Prefilled Nebulizers

Common Name: Nebulizer

Classification Name: Nebulizer (Direct Patient Interface), CFR – 868.5630, Class II

E. Device Description

Hudson RCI® AquaPak® Prefilled Nebulizers provide sterile water or sterile saline for inhalation therapy. Nebulizers generate aerosol, a fine mist of liquid water (or sodium chloride solution) that is suspended in the gas to be inhaled by the patient.

The Hudson RCI® AquaPak® Prefilled Nebulizers are designed to aerosolize and provide a fine mist of sterile water or saline solution to inspired gas during aerosol therapy.

Prefilled sterile reservoirs for AquaPak® Nebulizers come in three sizes; 440ml, 760ml and 1070ml. Each reservoir must be used with a suitable adaptor component, which connects the system to a flow-metered gas source and provides nebulizer functionality.

Section 29 – 510(k) Summary - Updated

Adaptor types available for the Hudson RCI® AquaPak® Prefilled Nebulizers include the 028 and the 033 Nebulizer Adaptors. Both the standard model with the yellow collar (type 028) and the quiet model with the blue collar (type 033) feature an adjustable air entrainment window, which provides a specific oxygen concentration by entraining room air into the oxygen stream.

F. Indications for Use

The **Hudson RCI® AquaPak® Prefilled Nebulizer** adds sterile water or saline solution in aerosol form to a patient's breathing gases.

G. Target Population

The **Hudson RCI® AquaPak® Prefilled Nebulizer** may be used with pediatric (ages 2 years and above) and adults.

H. Environments of Use

This device is intended for hospital, sub-acute facilities, long-term care facilities and in a home care environment.

This product is single use only.

I. Contraindications

There are no known contraindications.

J. Comparative Characteristics

The proposed Hudson RCI® AquaPak® Prefilled Nebulizer is substantially equivalent to the predicate device:

Comparative Characteristics	**Proposed Device: Hudson RCI® AquaPak® Prefilled Nebulizer**	**Predicate Device: Smiths Medical Portex™ Thera-Mist® Large Volume Nebulizer**
Manufacturer	**Teleflex Medical, Inc.**	**Smiths Medical ASD, Inc.**
510(k) Number	**TBD**	**K962534**
Indications for Use	**The Hudson RCI® AquaPak® Prefilled Nebulizer adds sterile water or saline solution in aerosol form to a patient's breathing gases.**	**The Smiths Medical Portex™ Thera-Mist® Large Volume Nebulizer delivers particulate humidity in the 3 to 5 micron range for chronic secretion patients.**

Principle of Operation	**Jet nebulizer with adjustable air entrainment**	**Jet nebulizer with adjustable air entrainment**
Gas source	**50 Psi oxygen regulated via a flow meter**	**50 Psi oxygen regulated via a flow meter**
Flow rate and FiO2 Control Capabilities	**<u>028 Model:</u> 28% at 5 LPM 35% at 8 LPM 40% - 98% at 10 LPM <u>033 Model:</u> 28% - 35% at 8 LPM 40% - 98% at 10 LPM**	**<u>Normal Flow LVN:</u> 28% - 60 % <u>High Flow LVN:</u> 36% - 95% at 14 – 15 LPM**
Aerosol Particle Size Delivery	**1.5 to 3 micron range**	**3 to 5 micron range**
Sterilization	**Adaptors – Non-sterile Sterile Water/Saline Reservoirs - Reverse osmosis, distillation, and aseptic fill**	**Adaptors – Non-sterile Sterile Water/Saline Reservoirs - Reverse osmosis, distillation, and aseptic fill**
Single Use	**Yes**	**Yes**
Shelf Life	**Adaptors – N/A Sterile Water/Saline – 2 years from date of manufacture**	**Adaptors – N/A Sterile Water/Saline – 2 years from date of manufacture**
Packaging	**Adaptors – 50/case, 10 or 20/case when packaged with water/ saline Sterile water/saline – 10 or 20/case**	**LVN Adaptors – 40/case, 12/case when packaged with water Sterile Water – 12/case Saline – Made-to-Order**

K. Non-clinical Comparative Performance Testing

Bench testing has been performed to verify that the performance of the proposed **Hudson RCI® AquaPak® Prefilled Nebulizer** is substantially equivalent to the predicate device, and that the **Hudson RCI® AquaPak® Prefilled Nebulizer** will perform as intended.

Section 29 – 510(k) Summary - Updated

Test Performed	Reference to Standard (if applicable)	Principle of Test
Lift Pressure	N/A	Measures the amount of negative pressure required to pull liquid up for nebulization
Oxygen Entrainment	N/A	Measures the percentage of oxygen/air mixture when adjusted to preset oxygen percentage
Nebulization Rate	N/A	Determines the basic rate at which the liquid is aerosolized and emitted in mL/min
Particle Size Distribution	N/A	Determines the particle size (MMAD) and geometric standard deviation (GSD) of the aerosolized liquid

L. Substantial Equivalence

The proposed **Hudson RCI® AquaPak® Prefilled Nebulizer** is substantially equivalent in intended use, design, performance and principles of operation to the identified predicate device cleared under 510(k) K962534. The differences between the proposed **Hudson RCI® AquaPak® Prefilled Nebulizer** and the predicate device are minor and raise no new issues of safety and efficacy. The proposed **Hudson RCI® AquaPak® Prefilled Nebulizer** is substantially equivalent to the currently marketed predicate device.